



Docket No.: 0010-1075-0 PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: :
Hiroshi MATSUI, et al. : EXAMINER: FRONDA
SERIAL NO.: 09/462,472 :
FILED: JANUARY 14, 2000 : GROUP ART UNIT: 1652
FOR: METHOD FOR PRODUCING PURINE NUCLEOSIDE BY FERMENTATION

PETITION TO THE COMMISSIONER UNDER 37 C.F.R. §1.144

COMMISSIONER FOR PATENTS
ALEXANDRIA, VA 22313-1450

SIR:

Petitioners respectfully petition the Commissioner to review and withdraw the Election of Species Requirement set forth in the Restriction Requirement issued on June 21, 2001. In so doing, Petitioners respectfully request that the Commissioner direct the Examiner to expand the scope of examination to include the non-elected members of the Markush group of Claim 13. The facts of this case are as follows.

A Restriction Requirement was mailed in this application on June 21, 2001, asserting that the application contains inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1 (paper number 7). On the basis of this assertion, the Office required restriction as follows¹:

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¹ Claims 6 and 7 were omitted from the Restriction Requirement, but have been withdrawn as reading on a non-elected invention.

- Group I: Claim 1, drawn to a microorganism belonging to the genus *Escherichia* and having purine nucleoside-producing ability;
- Group II: Claim 2, drawn to a microorganism belonging to the genus *Escherichia* which has acquired a purine nucleoside-producing ability because of an increase of an activity of an enzyme involved in purine nucleoside biosynthesis;
- Group III: Claim 3, drawn to a microorganism belonging to the genus *Escherichia* which has acquired a purine nucleoside-producing ability because of an increase of an expression amount of a gene for an enzyme involved in purine nucleoside biosynthesis;
- Group IV: Claims 4, 5, and 8, drawn to a microorganism belonging to the genus *Escherichia* which has acquired a purine nucleoside-producing ability because deregulation of control of an enzyme involved in purine nucleoside biosynthesis;
- Group V: Claims 9 and 10, drawn to a microorganism belonging to the genus *Escherichia* which has acquired a purine nucleoside-producing ability because of a blockage of a reaction branching from purine nucleoside biosynthesis and leading to another metabolite;
- Group VI: Claims 11 and 12, drawn to a microorganism belonging to the genus *Escherichia* which is enhanced in purine nucleoside-producing ability by weakening of incorporation of a purine nucleoside into cells of the microorganism; and
- Group VII: Claim 13, drawn to a method for producing a purine nucleoside by fermentation comprising culturing a microorganism belonging to the genus *Escherichia*.^{2, 3}

In addition, the Examiner also required election of a single disclosed species of an enzyme from the following: succinyl-adenosine monophosphate synthase, purine nucleoside phosphorylase, adenosine deaminase, inosine-guanosine kinase, guanosine monophosphate reductase, 6-phosphogluconate dehydrase, phosphoglucose isomerase, adenine deaminase, and xanthosine phosphorylase.

² Claims 14-26 were added in the Amendment and Request for Reconsideration filed on December 14, 2001 and read on the elected invention.

³ Claim 27 was added in the Amendment and Request for Reconsideration filed on March 12, 2003 and read on

A Response was timely filed on July 13, 2001, electing, with traverse, Group VII (Claim 13) and phosphoglucose isomerase as a single disclosed species (current Claims 1, 9, 10, and 13-22, 25, and 27 read on the elected species).

The Restriction Requirement was properly traversed on the grounds that examination on the merits of the entire application would not present a serious burden upon the Examiner and, as such, “the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.” (MPEP §803) Moreover, Petitioners noted that evidence of the absence of a burden upon the Examiner is provided by the fact that the International Searching Authority had already examined all of the claims (including the species contained therein) together. Therefore, the Office has not applied the same standard of unity of invention as the International Preliminary Examination Authority (see the International Preliminary Examination Report). The Authority did not take the position that unity of invention was lacking in the International application and examined all claims together.

Petitioners note that PCT Article 27(1) states:

No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.

As such, the Office has failed to make out and/or apply a proper case for restriction.

Regarding the Election of Species Requirement, Petitioners offer the following:

Claim 13 provides a method for producing a purine nucleoside by fermentation comprising culturing a microorganism in a culture medium to produce and accumulate the purine nucleoside in the medium, and collecting the purine nucleoside, wherein the microorganism belongs to the genus *Escherichia* and has purine nucleoside-producing ability

the elected invention.

arising from inhibition of a reaction branching from purine nucleoside biosynthesis, and leading to another metabolite, in said microorganism, wherein said reaction is catalyzed by an enzyme selected from the group consisting of succinyl-adenosine monophosphate synthase, purine nucleoside phosphorylase, adenosine deaminase, inosine-guanosine kinase, guanosine monophosphate reductase, 6-phosphogluconoate dehydrase, phosphoglucose isomerase, adenine deaminase, and xanthosine phosphorylase.

On June 21, 2001, the Examiner required an election of single disclosed species from the members of the Markush group above. In electing phosphoglucose isomerase, Petitioners directed the Examiner's attention to the fact that the Examiner's statement that the species lack unity of invention is incorrect (see Response to Restriction and Election of Species Requirement filed July 13, 2001). Specifically, Petitioners noted that

According to the PCT administrative instructions in MPEP, Annex B, Part I (f), the requirement of the same special technical feature as defined in PCT Rule 13.2 is considered to be met when the alternatives of a Markush group are of similar nature. Here, the enzymes have a common activity because they catalyze the reaction branching from the purine nucleoside biosynthesis. In addition, the compounds of the Markush group belong to a recognized class of chemical compounds in the art to which the invention pertains. All compounds are enzymes.

Despite the foregoing, the Examiner maintained the Election of Species Requirement for the members of the Markush group. Therefore, Petitioners reminded the Examiner that MPEP §803.02 *compels* examination of all the members of the Markush group in a situation like the present case

On the basis of the foregoing, Petitioners respectfully petitioned the Commissioner to review and withdraw the Restriction Requirement of June 21, 2001 on March 22, 2004. Petitioners also respectfully request that the Commissioner direct the Examiner to expand the scope of examination to include the non-elected members of the Markush group of Claim 13

in accordance with MPEP §803.02.

In response to the Petition filed on March 22, 2004, the Petition's Examiner granted-in-part Applicants Petition by merging original Groups I-VI into new Group I and maintaining original Group VII as new Group II. In addition, the Petition's Examiner maintained the Election of Species Requirement.

The basis for maintaining the Election of Species Requirement is that: (1) burdensome search is not a requirement for restriction under lack of unity of invention, (2) the position taken by the International Authority holding unity to be satisfied is irrelevant to the U.S. Patent Office, (3) the species election is proper because "all the enzymes do not share a common structure and at least one Markush alternative is not novel over the prior art. Specifically, Seeger et al... teach the enzyme xanthosine phosphorylase as claimed and Mori et al... teach the enzyme inosine-guanosine kinase as claimed," and (4) MPEP §803.02 does not apply to National Stage (371) applications.

Petitioners disagree with at least positions (2) and (3) set forth by the Petition's Examiner.

With respect to position (2), the Office is again referred to PCT Article 27(l), which states:

No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.

As is already of record, the International Preliminary Examination Authority already reviewed the very claims that the U.S. Patent Office issued a Restriction and Election of Species Requirement over. The International Preliminary Examination Authority, examining under the unity of invention standard, did not take the position that unity of invention was

lacking in the International application and examined all claims together. However, the U.S. Patent Office, supposedly applying the same rules, found unity lacking. How then can this be reconciled? The only rationale is that the U.S. Patent Office has not applied the same standard of unity of invention as the International Preliminary Examination Authority. Petitioners kindly request that the U.S. Patent Office reconsider its position with respect to unity of invention.

Further, with respect to position (3), Petitioners submit that the Office has improperly applied the standard set forth in Annex B of the Administrative Instructions with respect to the Markush-type claims. PCT administrative instructions in the MPEP, Annex B, Part 2(f) specify that when examining Markush-type claims: "the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature." MPEP, Annex B, Part 2(f) further states:

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B) (1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

(B) (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

ii) In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

(iii) In paragraph (f)(i)(B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

As stated above, the Petition's Examiner previously held that the members of the Markush group fail to meet the unity of invention standard, because all members fail to share a common structure. However, from the foregoing, it is clear that not all members of a Markush group need a common structure. Unity is also present where "all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains."

In the present application, each member of the Markush group is recognized by the skilled artisan to be members of a recognized class of chemical compounds in the art to which the invention pertains as each of the members are enzymes that catalyze reactions that branch from the purine nucleoside biosynthetic pathway. Further, Petitioners submit that based on the disclosure in the present specification, the skilled artisan would expect that each of the listed enzymes would behave in the same way in the context of the claimed invention.

Moreover, with respect to novelty, Petitioners note that each of the cited references merely disclose the enzyme *per se*. None of these references disclose or suggest the use of an *Escherichia* microorganism in which the reaction catalyzed by the enzyme is inhibited, much less that the inhibition thereof is used for the enhanced production of a purine nucleoside. As stated above, novelty of the present invention does not lie in the identity of the sequences *per se*, but rather in the method and novel effect flowing therefrom. Therefore, the cited references do not show that any of the Markush alternatives is not novel when in the context of the claimed invention.

To this end, novelty should be determined based on whether the claimed invention of

using the enzyme is novel or not. In other words, novelty cannot be considered by extracting a single element from the claim and looking at this element of isolation. Novelty must be determined contextually. If the enzyme *per se* must be novel irrespective of the context of the claimed invention, a Markush expression could not be allowed in any invention that is directed to a new combination of known components. For example, if a claim were presented to an apparatus sealing automotive glass and an element of the claim were a fastener selected from the group consisting of a nail, a screw, a tack, and chewing gum, it would be unreasonable for the Office to say that these Markush members are not capable of being examined together because each of a nail, a screw, a tack, and chewing gum were known in the art. Certainly the proper way to examine this is whether these members were used in the appropriate context. To examine novelty any other way would be unreasonable, contrary to administrative efficiency, and inconsistent with the PCT administrative instructions.

Further, with respect to administrative efficiency, in an attempt to justify the recent proposed rule change package with respect to Continuation Practice (71 *Fed. Reg.* 48 (03 January 2006)), Director Dudas recently pointed to continuation applications as the primary cause of the backlog at the U.S. Patent Office. Director Dudas blamed the filing of multiple applications for the same invention as leading to an increase in inefficiency as Examiners are being forced to reexamine applications that have previously been filed, searched, and examined. However, the Office's position in this application seems to feed directly into this perceived problem. In this case, requiring Applicants to file multiple applications for the same invention would be a needless burden upon the Office resources.

In view of the foregoing, Petitioners submit that the Election of Species Requirement is improper and should be withdrawn.

An early and favorable indication of such action is earnestly solicited.

Respectfully submitted,

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